MAR 16 2005

K043491

Summary of Safety and Effectiveness 510(k) K

1.0 Basic Information

Submitter

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Date Prepared:
December 14 2004

Device Name: Enfant™
Classification Name: Electroencephalograph, Evoked Response
Common/Usual Name: Electroencephalograph , Evoked Potential (VEP) System
Regulatory Class: II
Panels: Neurology
Number: 882.1400 Electroencephalograph
882.1420 Electroencephalograph (EEG) Signal Spectrum Analyzer
882.1890 Stimulator, Photic, Evoked Response
Product codes: GWE, GWQ,GWL

1.1 Identification of Legally Marked Device

The Enfant™ System is substantially equivalent to the Maculoscope and the Espion System(K863956) both manufactured by Doran (aka Diagnosys LLC) and the VERIS system(K983983) manufactured by Electro-Diagnostic Imaging, Inc. These are hardware and software products. The Enfant™ device is substantially equivalent to the predicate devices with regard to device features and specifications, as well as intended use. All devices are visual evoked response test systems with similar operating requirements that are based on standard clinical procedures. Devices consist of hardware and software to provide a photopic stimulus and EEG capture and analysis of the evoked response. Diopsys purchased the assets of NEUROSCIENTIFIC CORP. Registration number 2434082. The EEG amplifier is an updated version of the amplifier used on the Venus System (K880773). The updates include modification for EMC and obsolete parts.

1.2 Device Description

Horizontal Contrast Photopic stimuli are presented to the patient on a computer monitor at various numbers of elements in separately stimulated fields. The fields

are varied in spatial size over a number of cycles. The signals are analyzed by the software using algorithms for spatial filtering and artifact rejection. Data may be presented in number form and on a graph. The device also adds some attention features specifically for children. In particular, a cartoon is presented prior to the VEP pattern. During the Cartoon presentation no data is collected. Age appropriate music is also presented to patient as well. The music is only intended as an attention facilitator.

1.3 Intended Use

The **Enfant** is a non-invasive medical device to screen, without dilation or sedation, for visual disorders in infants and pre-school children. The system uses Visual Evoked potentials to provide information about the visual pathway function and about optical or neural abnormalities related to vision.

1.4 Comparison to Cleared Devices

Feature	Enfant	RETIscan K023525	Veris K983983	Doran Maculoscope K863956	Venus System K880773
Generate photic signals and measure and display the electrical response generated by the visual nervious system	**YES**	**YES**	**YES**	**YES**	**Yes**
Electrophysiological Test Unit for quantifying the response, measuring a parameter (VEP) related to the response	**YES**	**YES**	**YES**	**YES**	**Yes**
Intended Populations Patients with suspected ophthalmic conditions	**YES**	**YES**	**YES**	**YES**	**Yes**
Intended Use	**YES**	**YES**	**YES**	**YES**	**Yes – Research Use Only**
Environment Hospitals, clinics and physician officies	**YES**	**YES**	**YES**	**YES**	**Yes**
Physiological Data Collected (VEP)	**YES**	**YES**	**YES**	**YES**	**YES**

1.5 Performance Data

The Enfant system has been tested and reviewed to the following standards listed below.

1.5.1 EN 60601-1:2003 and CAN/CSA C22.2 No. 601.1 General Requirements for Safety.

1.5.2 IEC 60601-1-2 :2001 Collateral Standard: Electromagnetic Compatibility

1.5.3 IEC 60601-1-4 The safety of equipment incorporating programmable electronic system

1.5.4 IEC 60601-2-26:2002 Particular Requirements for Safety of Electroencephalographs

1.5.5 IEC 60601-2-40:1998 Particular Requirements for Safety –Specifications for Electromyographs and Evoked Response Equipment.

1.6 Clinical performance data and support of effectiveness

An IRB approved clinical study confirmed the effectiveness of the Enfant system in detection of visual deficits in the form of children's response to VEP. The study has been accepted for publication by the *Journal of American Association for Pediatric Ophthalmology and Strabismus*. The study is expected to be in the February 2005 issue.

Methods: A new, "child-friendly" visual evoked potential (VEP) system (Enfant™ Diopsys, Inc., Pine Brook, NJ) for use in screening. 122 children, aged 6 months to 5 years, were tested, comparing test results in masked fashion to results of standard ophthalmologic examinations. A statistical program analyzed VEP differences between fellow eyes to determine a "pass" or "fail" for each child. For verbal patients, clinical amblyopia was defined as an interocular difference of two or more lines in best corrected visual acuity. For preverbal patients, clinical amblyopia was defined by the clinician's decision to treat with occlusion or atropine penalization. Preverbal children with significant refractive errors or structural eye pathology were also considered clinical positives.

Results: The test was completed by 94% of the test sample, each child requiring an average of 10 minutes to complete testing of both eyes. The sensitivity was 0.973, specificity 0.808, positive predictive value 0.706, and the negative predictive value 0.984

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 16 2005

Mr. Joseph Fontanetta
President
Diopsys, Inc.
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Pine Brook, New Jersey 07058

Re: K043491
Trade/Device Name: Enfant™
Regulation Number: 21 CFR 882.1890
Regulation Name: Evoked response photic stimulator
Regulatory Class: II
Product Code: GWE
Dated: February 17, 2005
Received: February 18, 2005

Dear Mr. Fontanetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043491

Device Name: Enfant

Indications For Use: The Enfant is a non-invasive medical device to screen, without dilation or sedation, for visual disorders in infants and pre-school children. The system uses Visual Evoked potentials to provide information about the visual pathway function and about optical or neural abnormalities related to vision.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature], MD

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) K043491